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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

RUTGERS, THE STATE UNIVERSITY
OF NEW JERSEY,

Plaintiff,

v.

QIAGEN N.V. and QIAGEN, INC.,

Defendants.

Case No.:

COMPLAINT

JURY DEMAND

This action is brought by Rutgers, The State University of New Jersey (“Rutgers”), an institution of higher education with its principal place of business at 7 College Avenue, New Brunswick, New Jersey 08901. Rutgers is the exclusive owner of United States patents covering methods and compositions for the detection in humans exposed to the mycobacterium that causes tuberculosis (*Mycobacterium tuberculosis*) (“TB”), wherein such methods and compositions discriminate between infection by *Mycobacterium tuberculosis* and vaccination by the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*. Rutgers brings this action against Qiagen N.V. and Qiagen, Inc. (collectively “Qiagen”) for infringement, contributory infringement, and/or inducement of infringement of those patents. Rutgers, by its attorneys, for its Complaint against Defendants alleges that:

The Parties

1. Plaintiff an institution of higher education with its principal place of business at 7 College Avenue, New Brunswick, New Jersey.

2. On information and belief, defendant Qiagen N.V. is a Dutch limited liability company doing business in the United States through its subsidiary, Qiagen, Inc.

3. On information and belief, defendant Qiagen, Inc. is a California corporation with its principal place of business in Germantown, Maryland.

Jurisdiction and Venue

4. This cause of action for patent infringement arises under the patent laws of the United States, Title 35, United States Code.

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this case involves patent infringement, and arises under the laws of the United States, 15 U.S.C. § 1051, *et seq.*

6. This Court has personal jurisdiction over Qiagen because Qiagen has committed acts of infringement within this District. Qiagen manufactures, uses, sells, and/or offers to sell in, and/or imports into, the United States, *in vitro* diagnostic kits for the detection of TB infection, including both QuantiFERON-TB Gold (“QFT”) and QuantiFERON-TB Gold Plus (“QFT-Plus”).

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

Background

8. Rutgers’ inventor Maria L. Gennaro, M.D. discovered novel methods and compositions for the detection of TB infection in humans. These methods and compositions discriminate between humans that have been exposed to TB versus those that have been

vaccinated with BCG. The patented inventions claim *in vitro* methods and compositions for the detection of TB infection in humans, in which a blood sample is drawn and then exposed to certain polypeptide antigens that are *Mycobacterium tuberculosis*-specific and are not found in BCG. The specific polypeptide antigens are recognized by T-cells of a person previously exposed to or infected with TB, prompting the T-cells to secrete cytokines, including interferon- γ (“IFN- γ ”). Detection of IFN- γ with an agent, such as an antibody, allows for diagnosis of TB exposure and/or infection in humans.

9. Both QFT and QFT-Plus, like the patented inventions, involve exposing a blood sample to certain peptide antigens to stimulate expression of IFN- γ by T-cells. The detection of expressed IFN- γ is accomplished using an enzyme-linked immunosorbent assay (“ELISA”) technology in both QFT and QFT-Plus.

10. On August 25, 2009, the U.S. Patent and Trademark Office issued U.S. Patent No. 7,579,141, titled “Proteins Expressed By *Mycobacterium tuberculosis* And Not By BCG And Their Use As Diagnostic Reagents And Vaccines (“the ‘141 patent”). A true and correct copy of the ‘141 patent is attached hereto as Exhibit A. Rutgers is the assignee and owner of all right, title and interest in the ‘141 patent.

11. On September 20, 2011, the U.S. Patent and Trademark Office issued U.S. Patent No. 8,021,832, titled “Proteins Expressed By *Mycobacterium tuberculosis* And Not By BCG And Their Use As Diagnostic Reagents And Vaccines (“the ‘832 patent”). A true and correct copy of the ‘832 patent is attached hereto as Exhibit B. Rutgers is the assignee and owner of all right, title and interest in the ‘832 patent.

12. On March 10, 2015, the U.S. Patent and Trademark Office issued U.S. Patent No. 8,974,800, titled “Proteins Expressed By *Mycobacterium tuberculosis* And Not By BCG

And Their Use As Diagnostic Reagents And Vaccines (“the ‘800 patent”). A true and correct copy of the ‘800 patent is attached hereto as Exhibit C. Rutgers is the assignee and owner of all right, title and interest in the ‘800 patent.

COUNT I
(Infringement of the ‘141 patent)

13. Rutgers incorporates by reference the factual allegations contained in paragraphs 1 through 12 of this complaint, as if fully set forth herein.

14. Defendants are, and have been, on notice of the ‘141 patent, a least as of the filing of this lawsuit.

15. By making, using, selling, and/or offering to sell in, and/or importing into, the United States, QFT and QFT-Plus, Qiagen has directly infringed and continues to directly infringe one or more claims of the ‘141 patent, under 35 U.S.C. § 271(a).

16. Qiagen is actively inducing infringement of one or more claims of the ‘141 patent by others, by among other things, actively inducing and encouraging others to make, use, test, sell, offer to sell in, and/or import into the United States, at least QFT and QFT-Plus. Qiagen has known of the ‘141 patent at least as of the filing of this Complaint, and knows and intends, or is willfully blind to the fact, that the actions of these direct infringers so induced constitute infringement of one or more claims of the ‘141 patent. Thus, Qiagen is liable for infringement under U.S.C. § 271(b).

17. Qiagen is contributorily infringing the ‘141 patent by selling, and/or offering to sell in, and/or importing into, the United States, without authority, a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, such as QFT and QFT-Plus, knowing the same are especially made or especially adapted for use in an

infringement of one or more claims of the '141 patent. Both QFT and QFT-Plus are not a staple article or commodity of commerce suitable for substantial non-infringing use. At all times relevant to this Complaint, and at least as of the filing of this Complaint, Defendants knew that both QFT and QFT-Plus are especially made or especially adapted for use that infringes the '141 patent, particularly because both QFT and QFT-Plus use the polypeptides claimed by the '141 patent. Thus, Qiagen is liable for infringement under U.S.C. § 271(c).

18. All of the aforementioned infringing acts by Defendants are without the permission, license, or consent of Rutgers.

19. All of the aforementioned infringing acts by Defendants have been, and continue to be, willful and deliberate, and Rutgers believes that such acts will continue in the future unless Defendants are enjoined by this Court.

20. By reason of Defendants' acts of infringement, they have been unjustly enriched.

21. By reason of Defendants' acts of infringement, Rutgers has suffered and will continue to suffer irreparable harm and damages, including, but not limited to diminution of the value of the '141 patent, in an amount to be determined.

22. As a result of the continuing harm to Rutgers and the diminution of the value of the '141 patent, Rutgers has no remedy at law.

COUNT II
(Infringement of the '832 patent)

23. Rutgers incorporates by reference the factual allegations contained in paragraphs 1 through 22 of this complaint, as if fully set forth herein.

24. Defendants are, and have been, on notice of the '832 patent, a least as of the filing of this lawsuit.

25. By making, using, selling, and/or offering to sell in, and/or importing into, the United States, QFT and QFT-Plus, Qiagen has directly infringed and continues to directly infringe one or more claims of the '832 patent, under 35 U.S.C. § 271(a).

26. Qiagen is actively inducing infringement of one or more claims of the '832 patent by others, by among other things, actively inducing and encouraging others to make, use, test, sell, offer to sell in, and/or import into the United States, QFT and QFT-Plus. Qiagen has known of the '832 patent at least as of the filing of this Complaint, and knows and intends, or is willfully blind to the fact, that the actions of these direct infringers so induced constitute infringement of one or more claims of the '832 patent. Thus, Qiagen is liable for infringement under U.S.C. § 271(b).

27. Qiagen is contributorily infringing the '832 patent by selling, and/or offering to sell in, and/or importing into, the United States, without authority, a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, such as QFT and QFT-Plus, knowing the same are especially made or especially adapted for use in an infringement of one or more claims of the '832 patent. Both QFT and QFT-Plus are not staple articles or commodity of commerce suitable for substantial non-infringing use. At all times relevant to this Complaint, and at least as of the filing of this Complaint, Defendants knew that QFT and QFT-Plus are especially made or especially adapted for use that infringes the '832 patent, particularly because QFT and QFT-Plus both use the polypeptides claimed by the '832 patent. Thus, Qiagen is liable for infringement under U.S.C. § 271(c).

28. All of the aforementioned infringing acts by Defendants are without the permission, license, or consent of Rutgers.

29. All of the aforementioned infringing acts by Defendants have been, and continue to be, willful and deliberate, and Rutgers believes that such acts will continue in the future unless Defendants are enjoined by this Court.

30. By reason of Defendants' acts of infringement, they have been unjustly enriched.

31. By reason of Defendants' acts of infringement, Rutgers has suffered and will continue to suffer irreparable harm and damages, including, but not limited to diminution of the value of the '832 patent, in an amount to be determined.

32. As a result of the continuing harm to Rutgers and the diminution of the value of the '832 patent, Rutgers has no remedy at law.

COUNT III
(Infringement of the '800 patent)

33. Rutgers incorporates by reference the factual allegations contained in paragraphs 1 through 32 of this complaint, as if fully set forth herein.

34. Defendants are, and have been, on notice of the '800 patent, a least as of the filing of this complaint.

35. By making, using, selling, and/or offering to sell in, and/or importing into, the United States, QFT, Qiagen has directly infringed and continues to directly infringe one or more claims of the '800 patent, under 35 U.S.C. § 271(a).

36. Qiagen is actively inducing infringement of one or more claims of the '800 patent by others, by among other things, actively inducing and encouraging others to make, use, test, sell, offer to sell in, and/or import into the united States, at least QFT. Qiagen has known of the '800 patent at least as of the filing of this Complaint, and knows and intends, or is willfully blind to the fact, that the actions of these direct infringers so induced constitute

infringement of one or more claims of the '800 patent. Thus, Qiagen is liable for infringement under U.S.C. § 271(b).

37. Qiagen is contributorily infringing the '800 patent by selling, and/or offering to sell in, and/or importing into, the United States, without authority, a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, such as QFT, knowing the same is especially made or especially adapted for use in an infringement of one or more claims of the '800 patent, including at least claim 1. QFT is not a staple article or commodity of commerce suitable for substantial non-infringing use. At all times relevant to this Complaint, and at least as of the filing of this Complaint, Defendants knew that QFT is especially made or especially adapted for use that infringes the '800 patent, particularly because QFT uses the polypeptides claimed by the '800 patent. Thus, Qiagen is liable for infringement under U.S.C. § 271(c).

38. All of the aforementioned infringing acts by Defendants are without the permission, license, or consent of Rutgers.

39. All of the aforementioned infringing acts by Defendants have been, and continue to be, willful and deliberate, and Rutgers believes that such acts will continue in the future unless Defendants are enjoined by this Court.

40. By reason of Defendants' acts of infringement, they have been unjustly enriched.

41. By reason of Defendants' acts of infringement, Rutgers has suffered and will continue to suffer irreparable harm and damages, including, but not limited to diminution of the value of the '800 patent, in an amount to be determined.

42. As a result of the continuing harm to Rutgers and the diminution of the value of the '800 patent, Rutgers has no remedy at law.

RELIEF SOUGHT:

WHEREFORE, Rutgers respectfully requests that this Court:

(1) Rule that Defendants' *in vitro* diagnostic kits for the detection of TB infection, including both QFT and QFT-Plus (products) infringe, contribute to the infringement, and/or induce the infringement of the '141, '832 and '800 patents;

(2) Grant a preliminary and/or permanent injunction against the continued infringement, contributory infringement, and/or induced infringement of the '141, '832 and '800 patents by Defendants and each of their agents, servants, employees, attorneys, officers, and all others in privity and acting in concert with them;

(3) Order an accounting to determine and assess against Defendant an award to fully compensate Rutgers for damages arising out of Defendant's infringement, contributory infringement, and/or induced infringement of the '141, '832 and '800 patents;

(4) Order that this case be deemed exceptional under 35 U.S.C. § 285;

(5) Award treble damages against Defendants by reason of the willful and deliberate nature of their infringement;

(6) Award Rutgers its costs and reasonable attorneys' fees incurred in this action;
and

(7) Grant Rutgers any such other, further, different, or additional relief as this Court deems just, equitable, and proper.

DEMAND FOR JURY TRIAL

Rutgers demands trial by jury on all issues triable to a jury.

Dated: September 30, 2015

Respectfully submitted,

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*Attorneys for Plaintiff Rutgers, The State
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Plaintiff, Rutgers, the State University of New Jersey, certifies that, to the best of his knowledge, the matters in controversy are not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 30, 2015

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